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510(k) SUMMARY

AUG 31 2007

Dominator™

Applicant Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person Mr Simon Fitzer
Tel: +44 (0) 1782 338580
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Classification Name:	Smooth or threaded metallic bone fixation fastener
Common/Usual Name:	Suture anchor, bone anchor
Trade/Proprietary Name	Dominator™
Product Code	HWC, JDR

Device Description

Dominator™ is a bioabsorbable device manufactured from a composite mixture of poly-L-lactic acid (PLLA) and calcium phosphate. It may be supplied with sutures with or without pre-attached needles.

Intended Use / Indications

Dominator™ has the exact same intended use and indications as the predicate device.
Dominator™ is intended for fixation of suture to bone in orthopaedic procedures.

The indications, contraindications, risks and potential adverse events are the same as the predicate device and is thus substantially equivalent.

Summary of Technology

Dominator™ has the same technological characteristics as the legally marketed predicate device and any differences do not raise concerns regarding safety and effectiveness.

Non Clinical Testing

Documentation provided demonstrates that the Dominator™ is substantially equivalent to the predicate device and any differences do not raise concerns regarding safety and effectiveness.

Substantial Equivalence

Documentation provided demonstrates that the Dominator™ is substantially equivalent to the legally marketed predicate device and any differences do not raise concerns regarding safety and effectiveness.

Safety and Performance

Documentation provided demonstrates that the Dominator™ is substantially equivalent to the legally marketed predicate device and any differences do not raise concerns regarding safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2007

Biocomposites Ltd
% Mr Simon Fitzer
Keele Science Park
Keele, Staffordshire
England
ST5 5NL

Re: K072127
Trade/Device Name: Dominator™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR
Dated: July 25, 2007
Received: August 2, 2007

Dear Mr. Fitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

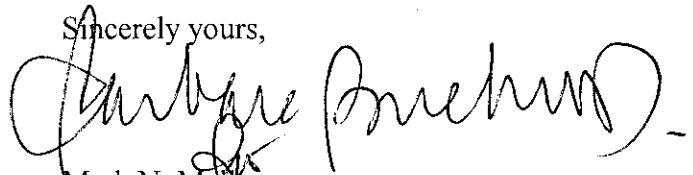
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Simon Fitzer

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or at the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Meekerson", written over a horizontal line.

Mark N. Meekerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072127

Device Name: Dominator™

Indications For Use:

Dominator™ is intended for fixation of suture to bone in orthopaedic procedures in the shoulder, foot/ankle, knee, hand/wrist, elbow and pelvis.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter use ☐
(Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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